Exam Code(s) 3BS9, 1OA, 3EV2
Exam(s) Third Science Examination
Module Code(s) CH327
Module(s) Industrial Chemistry and Validation

Instructions: Answer 2 questions from each section (4 questions in total)
Use separate books for each section

3BS9 Students answer questions from sections A and B only
1OA Students answer questions from sections A and B only
3EV2 Students answer questions from sections B and C only
All questions will be marked equally

Duration 2 hours
No. of Pages 9
Department(s) Chemistry
Course Co-ordinator(s) Dr. L. F. Jones

Requirements:
MCQ
Handout
Statistical Tables
Graph Paper
Log Graph Paper
Other Material
Section A

1. With respect to the manufacturing of pharmaceuticals and biopharmaceuticals discuss the concept of industrial validation and the role of the Validation Master Plan (VMP).

[25 Marks]

2. Discuss the important points concerning the topic of process validation with respect to the pharmaceutical manufacturing industry, highlighting the concepts of Design, Installation, Operational and Performance Qualification.

[25 marks]

3. Define and discuss fully the concept of Process Analytical Technology (PAT) with respect to the pharmaceutical and biopharmaceutical industry.

[25 Marks]

4. Answer all parts

   a) Briefly describe the Medical Device Directive system for Classification of medical devices. Give two examples of typical devices in each Class.

   [10 marks]

   b) List the fundamental factors that are considered in defining Classification for a device. What is the main implication of device Classification for the developer/manufacturer?

   [5 marks]

   c) List the key steps involved in obtaining approval to sell a medical device in the EU. In support of your answer give brief definitions for the Technical File and Notified Body.

   [10 marks]

5. Answer all parts

   a) Briefly outline (in your own words) the Global Harmonization Task Force definition of a medical device.

   [5 marks]

   b) Describe a Class III device (in accordance with Medical Device Directive), presenting two examples of typical devices that fit this category. List three key items required when submitting a Class III device for EU regulatory approval.

   [5 marks]
c) Describe the purpose of an Investigational Device Exemption (IDE), briefly indicating its’ main features

[5 marks]

d) Describe the difference between the pre-marketing submissions for Class II and III devices in the US.

[10 marks]
Section B

1. Answer all parts.

   a) What are the top two countries for chemical exports in Europe?

      [2 marks]

   b) Give examples of two uses which can push chemicals to the top of the chemical production list.

      [4 marks]

   c) Define the terms capital cost, conversion and selectivity.

      [6 marks]

   d) What are the most important differences between laboratory based procedures and the procedures used in industry?

      [8 marks]

   e) Which of the following are in the top five chemicals list for inorganic chemicals and organic chemicals respectively?

      Inorganic: Cl₂, NaOH, H₂SO₄, HCl, NH₃.
      Organic: Analine, Urea, Styrene, Ethylenedichloride, aspirin.

      [5 marks]

2. Answer all parts

   a) Environmental concerns and energy costs have been the major driving forces in the development of new electrode and cell technologies in the chlor-alkali industry. Discuss this statement.

      [15 marks]

   b) Describe the advantages and disadvantage of homogeneous and heterogeneous catalysis and the reactor types that suit each type of catalyst.

      [10 marks]
3. Answer all parts.

a) What is syn-gas and how is it obtained? [5 marks]

b) Describe the large scale catalytic production of ammonia from elemental nitrogen and hydrogen gas. [10 marks]

c) Describe the Ziegler process for the polymerisation of alkenes and compare the conditions of the process with those of the free radical process for alkene polymerisation.

What are the advantages offered by the recently developed metallocene catalysts? [10 marks]
Section C

1. **Answer all parts**
   a) Briefly explain, using diagrams, the following three main components of a mass spectrometer: (i) electron impact ionization, (ii) TOF separator and (iii) electron multiplier detector. In outlining the overall spectrometer it may be helpful to follow the species under examination from injection to detection.

   [10 marks]

   b) The electron impact ionisation spectrum of 4-bromoacetophenone is given below. Account for the major peaks (as indicated) in the spectrum and the fragmentation mechanisms which lead to the formation of the respective ions.

   ![Mass Spectrum of 4-bromoacetophenone](image)

   [10 marks]

   c) Bromine possesses two common isotopes $^{79}\text{Br}$ and $^{81}\text{Br}$. Evidence of this can be seen in the spectrum: outline the evidence for the two isotopes and comment on the relative ratio of the two isotopes present.

   [5 marks]
2. **Answer all parts**

   a) Explain the purpose and fundamental theory of chromatography using column chromatography as an example. In your answer explain the difference between adsorption, partition, ion and gel chromatography.

   [10 marks]

   b) A packed column is 4500 mm in length. It has a height equivalent of a theoretical plate of 1.4 mm. Calculate the width of the chromatographic peak with the retention time of 252 seconds.

   [10 marks]

   c) Name and describe three types of detectors used in Gas Chromatography and comment on their advantages and disadvantages.

   [5 marks]

3. **Answer all parts**

   a) Provide a schematic diagram of the HPLC system that would be required to carry out the analysis below.

   [5 marks]

   b) The column used is of the reverse (RP) type. Explain what is meant by this term and explain why knowing that the column used is of this type allows us to define which chemical species is the most polar and which is the least polar. Identify the most polar and least polar chemical species analysed.

   [8 marks]
c) What type of detector is used in this analysis? Draw a diagram and show how this type of detector works. [5 marks]

d) Explain, using a diagram, what a diode detector is and outline its advantages. [7 marks]

Anti-Inflammatory/Analgesics

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1. Amin
2. Paracetamol
3. Sublimes
4. Ibroxen

4. Answer all parts

a) Explain with the aid of a diagram the process of Auger Electron Emission, and how it impacts on XRF spectroscopy. [5 marks]

b) The Kα, Kβ and Lα lines of the x-ray fluorescent spectrum of chromium occur with energies (keV) 5.415, 0.573, and 5.947. Assign the correct energy to each of the lines and explain why you make the specific assignments. [5 marks]
c) Outline the construction and mode of operation of a standard single channel energy dispersive and a secondary target X-ray fluorescence spectrometers.

[6 marks]

d) Explain with the aid of diagrams why the XRF calibration plot for the iron content of a manganese steel is linear whereas plots for chromium and nickel steels are non-linear.

[9 marks]